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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,601

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Edward I. Wulfman

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2014-B East Union
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

03/29/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/798,601	Applicant(s) WULFMAN, EDWARD I.	
	Examiner MICHAEL G. MENDOZA	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,21 and 27-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,21 and 27-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/3/2010 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 2-17, 19, 21, and 27-35 have been considered but are moot in view of the new ground(s) of rejection.
3. The applicant had added new independent claims 29. The newly added claim changes the scope of the claim and requires new consideration.
4. Claims 1, 18, 20, and 22-26 have been cancelled.
5. Claims 29-35 are newly added.
6. Claims 2-17, 19, 21, 27-35 are currently pending.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2, 3, 5, 21, 27-29, 31, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Conley et al. 5527325.

9. Conley et al. teaches an intracorporeal medical device comprising: an operating head (40); a catheter comprising a tubular structure, the tubular structure comprising: an overlying layer (28) and a supporting layer (30) defining an internal lumen (37), wherein the support layer comprises a contiguous coil element, a braid element or a weave element including a plurality of loops (92), the support layer being attached to the overlying layer at a bonding point and not attached to the overlying layer along a free portion (col. 8, lines 9-14, col. 9, lines 47-53), whereby the support layer is slippable relative to the overlying layer along the free portion when the tubular structure is bent (fig. 8, space 33 between 30 and 28); and a drive shaft (32) extending within, and rotatable and translatable within, the internal lumen (37) of the catheter wherein the loops are moveable to reposition relative to each other as the tubular structure is bent (bending would cause movement of the braids); wherein the bonding point is at one end of the support layer (at 34) and the remaining portion of the support layer is the free portion; further comprising a drive system and a control system to direct rotation of the drive shaft (col. 13, lines 1-10); wherein the operating head comprises a cutter (72); wherein the catheter comprises a proximal section having the least flexibility (50), a mid section (52) and a distal section (22) having the most flexibility and the distal section comprises the tubular structure; and wherein the support layer incorporates a less flexible support element (34) at or near the bonding point; wherein the mid section includes a less flexible area that does not incorporate a support layer.

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10. Claim 30 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conley et al.

11. Claim 30 is a product-by-process claim. The claimed product appears to be the same or similar to that of the prior art, although produced by a different process. Claim 30 recites welding the support layer of the tubular structure to the operating head.

Conley et al. discloses melting the support layer to the operating head. Both processes result in the same product of the support layer being attached to the operating head.

12. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Conley et al. to attached the support layer to the operating head using welding, since welding is a mechanical expedient to melting the support layer to the operating head.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 4-7, 11-13, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al.

15. As to claim 4 Conley et al. teaches a device that is flexible yet resists crushing. Conley et al. fails to teach about what radius the device can go without kinking. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the flexibility of the device to a desired range before kinking, since it has

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been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. As to claims 5, 11, and 32-34, Conley et al. teaches the device of claim 29, wherein the overlying layer is formed as a thermally shrinkable sheath (col. 12, lines 24-30), and wherein the sheath encases and contacts the support layer and the support layer and sheath are slippable relative to one another along the free portion. It should be noted that Conley et al. fails to teach having a plurality of etches on at least its interior surface. Conley et al. teaches etches that it is known to etch a surface to improve adhesion of layers (col. 11, lines 17-22). Therefore, it would have been obvious to etch the surfaces of the overlying layer to promote the adhesion of the sheath to the overlying layer.

17. As to claims 6, 7, 12, and 13, Conley et al. teaches wherein the sheath comprises a polytetrafluoroethylene material; wherein the sheath comprises PTFE, Teflon[®], FEP and/or PFA (col. 11, lines 41-47).

18. Claims 8-10, 14, 15, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al. as applied to claims 4-19 and 32-35 above, and further in view of Bagaoisan et al. 6270477.

19. As to claims 8, 14, and 19, Conley et al. teaches the device of claim 6. It should be noted the Conley et al. fails to teach a contiguous coil element comprised of a wire and a plurality of gaps between each loop. Conley et al. teaches the use of braided wire to reinforce the support layer.

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20. Bagaoisan et al. teaches the use of a braided wire or coil having gaps (col. 7, lines 35-39) to reinforce a tubular body to prevent bucking or undesirable bending of the tubular body (col. 7, lines 13-16). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Conley et al. in view of Bagaoisan et al. to use a coiled wire as opposed to a braided wire, because the coiled wire is a mechanical expedient to a braided wire for reinforcing a tubular body.

21. As to claims 9 and 15, Conley/Bagaoisan teaches a device that is flexible yet highly resistant to kinking. Conley/Bagaoisan fails to teach the length of each gap being 10-200 percent of the width of the wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed gap range limitation, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

22. As to claim 16, Conley/Bagaoisan teaches the device of claim 10, wherein the sheath is bonded to the support layer at a bonding point located at one end of the sheath and the sheath is capable of slipping along the support layer as the tubular structure is bent (col. 8, lines 9-14, col. 9, lines 47-53).

23. As to claim 17 Conley/Bagaoisan teaches a device that is flexible yet resists crushing. Conley et al. fails to teach about what radius the device can go without kinking. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the flexibility of the device to a desired range before

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kinking, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734
March 27, 2011